

**Notice of Allowability**

Application No.

10/644,797

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

SIEGLER, KATHERINE MEYER

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1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07 November 2007.
2. ☒ The allowed claim(s) is/are 1-5, 11-15 and 23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

/Stephen L. Rawlings/  
Stephen L. Rawlings, Ph.D.  
Primary Examiner, Art Unit 1643

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Charles Wolfe, Jr., on November 19, 2007.
3. The application has been amended as follows:

In the claims:

The following set of claims has replaced the prior set of claims:

Claim 1. (Currently Amended) A method for detecting or diagnosing prostate cancer in an individual comprising the step of determining levels of macrophage migration inhibitory factor (MIF) and prostate specific antigen (PSA) in the serum of the individual; and detecting or diagnosing prostate cancer where the serum MIF levels are greater than about 5 to about 10 ng/ml and the PSA levels are elevated, as compared to PSA levels in serum from normal, unaffected individuals.

Claim 2. (Original) The method of claim 1, wherein the determining step is accomplished by immunoassay.

Claim 3. (Original) The method of claim 2, wherein the immunoassay is an ELISA.

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Claim 4. (Original) The method of claim 2, wherein the immunoassay is an immunoblot.

Claim 5. (Original) The method of claim 2, wherein the immunoassay is a protein array.

Claims 6-10. (Cancelled).

Claim 11. (Currently Amended) The method of claim 1, wherein the determining step comprises the steps of contacting the serum of the individual with a molecule that specifically binds ~~the macrophage~~ MIF; and detecting the presence of binding between ~~the macrophage~~ MIF and the molecule.

Claim 12. (Original) The method of claim 11, wherein the molecule is an antibody.

Claim 13. (Original) The method of claim 12, wherein the antibody is selected from the group consisting of monoclonal antibodies and polyclonal antibodies.

Claim 14. (Original) The method of claim 11, wherein the molecule is labeled.

Claim 15. (Currently Amended) The method of claim 14, wherein the label is selected from the group consisting of biotin, fluorescent molecules, radioactive molecules, chromogenic substrates, ~~chemiluminescence~~ chemiluminescent molecules, and enzymes.

Claims 16-22. (Cancelled).

Claim 23. (Original) The method of claim 1, further comprising the step of comparing the levels of MIF in the serum of the individual to the MIF levels of prostate cancer patients.

Claims 24-93. (Cancelled).

***Examiner's Statement of Reasons for Allowance***

4. The following is an examiner's statement of reasons for allowance:

Support for the amendment to claim 1 is found throughout the specification, as filed; see, e.g., paragraphs [0013], [0030] and [0057] of the published application (i.e., U.S. Application Publication No. 2004/0171021 A1).

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

6. Claims 1-5, 11-15, and 23 have been allowed.

7. Claims 11-15 and 23 have been renumbered as claims 6-11, respectively.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/  
Stephen L. Rawlings, Ph.D.  
Primary Examiner  
Art Unit 1643

slr

November 28, 2007